IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants:	Castillo et al.
Serial No.:	09/079,829
Title of Invention:	COMPOSITION AND METHODS FOR TREATING ALZHEIMER'S DISEASE AND OTHER AMYLOIDOSES
Filing Date:	05/15/1998
Group Art Unit:	1651
Examiner:	Coe, S.
Attorney Docket No.:	PROTEO.P07

Seattle, Washington 98109
October 26, 2001

TO THE COMMISSIONER FOR PATENTS
Washington, D.C. 20231
Box BPAI

BRIEF OF APPELLANT

This is an appeal from the final rejection of the Examiner dated 4/24/2001 rejecting Claims 1-13 and 44-54. This Brief is accompanied by the requisite fee set forth in Rule 1.17(c).

STATUS OF CLAIMS (37 CFR 1.92(c)(1))

The application was filed on 5/15/1998 with forty three (43) claims of which three (3) were independent claims (Claims 1, 14 and 39).

In a Restriction Requirement dated 12/17/1999 the Examiner identified three claim groups: I, Claims 1-13, drawn to a composition comprising *Uncaria*, classified in class 424, subclass 195.1; II, Claims 14-38, drawn to a method for making an *Uncaria tomentosa* extract, classified in class 424, subclass 195.1; III, Claims 39-43, drawn to a method for treating amyloid diseases, classified in class 424, subclass 195.1. Appellant responded on 4/17/2000 electing Group I including Claims 1-13.

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service on the date shown below with sufficient postage as first class mail in an envelope addressed to the Commissioner of Patents and Trademarks, Washington, D. C. 20231.

October 26, 2001 Patrick Dwyer

All of the claims were rejected on 9/01/2000. In Appellant's response dated 2/01/01, Claims 14-43 were canceled and Claim 9 was amended. New Claims 44-54 were added, of which Claim 44 was independent. Claims 1-13 and 44-54 were finally rejected on 4/24/2001.

The status of claims on appeal is as follows:

Canceled claims: 14-43

Pending claims: 1-13, 44-54

Claims appealed: 1-13, 44-54

STATUS OF AMENDMENTS (37 CFR 1.92(c)(2))

There have been no amendments filed responsive to the Final Rejection; there have been no interviews with the Examiner since the Final Rejection.

SUMMARY OF THE INVENTION (37 CFR 1.192(c)(3))

The claims on appeal are directed to a pharmacological agent comprising a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, the plant matter and the therapeutic amount of the plant matter selected for efficacy in treating an amyloid disease in a patient, and to a pharmaceutical agent for treating an amyloid disease in a patient, wherein the pharmacological agent comprises a therapeutically effective amount of plant matter from a plant of the genus Uncaria.

Fibrillar Aß amyloid deposition, such as in Alzheimer's disease, is believed to be detrimental to the patient and eventually leads to toxicity and neuronal cell death. Accumulating evidence implicates amyloid as a major causative factor of Alzheimer's disease pathogenesis. A variety of other human diseases also demonstrate amyloid deposition and usually involve systemic organs (i.e. organs or tissues lying outside the central nervous system), with the amyloid accumulation likewise leading to organ dysfunction or failure. In Alzheimer's disease and "systemic" amyloid diseases, there is currently no cure or effective treatment, and the patient usually dies within 3 to 10 years from disease onset. Much work in Alzheimer's disease has been accomplished, but little is conventionally known about compounds or agents for therapeutic regimes to arrest amyloid formation, deposition, accumulation and/or persistence that occurs in Alzheimer's disease and other amyloidoses.

Uncaria tomentosa is not unknown in the pharmacopeia of useful plant substances; however there has never been a reference in the literature to its surprising effectiveness in arresting or reversing amyloid formation, deposition, accumulation and/or persistence that occurs in Alzheimer's disease and other amyloidoses. Exploration of its amyloid therapeutic properties was not motivated in any way by the literature on this plant substance; but for the seminal work of the inventors in this case, the world would not have available, as it does now, any of the work now made public on the encouraging potential of this substance to function as a non-prescription nutraceutical for the treatment of Alzheimer's disease and other amyloidoses.

New compounds or agents for therapeutic regimes to arrest or reverse amyloid formation, deposition, accumulation and/or persistence that occurs in Alzheimer's disease and other amyloidoses are therefore desperately needed, and there has never been a suggestion that *Uncaria tomentosa* would provide such surprisingly efficacy in treatment of amyloidosis.

ISSUES (37 CFR 1.192(c)(4))

1. Are Claims 5, 6, 9, 47 and 50 allowable under 35 USC §112, second paragraph, notwithstanding the use of parenthesis in the claims?

2. Are Claims 1-10, 12, 13, 44-51, 53 and 54 allowable under 35 USC 102(b) notwithstanding the citation by the Examiner of US Patent 4,940,725 to Keplinger as allegedly anticipating these claims?

3. Are Claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53 and 54 allowable under 35 USC 102(b) notwithstanding the citation by the Examiner of Stuppner as allegedly anticipating these claims?

4. Are Claims 1-3, 11, 44-46 and 52 allowable under 35 USC 103(a) notwithstanding the citation by the Examiner of Keplinger or alternatively Stuppner as allegedly rendering these claims obvious?

ARGUMENT (37 CFR 1.192(C)(6))

Issue 1 The rejection of Claims 5, 6, 9, 47 and 50 as unpatentable under 35 USC §112 because of the use of parenthesis in the claim.

Claims 5, 6, 9, 47 and 50 stand finally rejected under 35 USC §112, as allegedly indefinite. The Examiner takes the position that it is unclear whether or not the material in the

parentheses is to function as a limitation of the claim and that therefore the metes and the bounds of the claims cannot be definitely determined.

Applicant has already addressed the Examiner's concern about whether or not the parenthetic material in these claims is to be included in the claim or not by expressly affirming that all of the parenthetic material in each of these claims is to be included in the respective claim as limitations. Since each instance of the parenthetic material is an instance of example or particular, all of the parenthetic material is thus appropriately further limiting to the claim, and there is no citation of any authority to the contrary. Claims 5, 6, 9, 47 and 50 are therefore believed to be allowable under 35 USC §112, and reversal of this rejection by the Board is urged.

Issue 2 The rejection of Claims 1-10, 12, 13, 44-51, 53 and 54 under 35 USC 102(b) over Keplinger.

Claims 1-10, 12, 13, 44-51, 53 and 54 stand finally rejected under 35 USC 102b as allegedly anticipated by Keplinger. It is the Examiner's position that Keplinger illustrates that compositions containing *Uncaria tomentosa* are known, and that Applicants merely state that the claimed composition is used for a different purpose, which is not persuasive because the claimed purposes are considered by the Examiner as recitations of intended use. The Examiner argues that recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. The Examiner takes the position that Appellants' claims are drawn to a composition comprising *Uncaria tomentosa* that is identical to the composition taught by Keplinger, and that the reference composition would "inherently" have the same effect on the human body as that claimed by Applicants.

Applicant respectfully points out that Keplinger has nothing in common with the rejected claims except for the mention of the plant species *Uncaria tomentosa* and the oxindole alkaloids. The cited reference concerns itself only with stimulation of the human immunological system to increase resistance to viral and tumorous diseases, and not at all with Alzheimer's disease or any other amyloidosis. In contrast, Applicant has developed and disclosed entirely new and previously undisclosed technology in the nutraceutical and pharmaceutical fields of treatment of Alzheimer's disease and other amyloidoses in patients by the introduction of selected therapeutic quantities of

Uncaria and *Uncaria tomentosa* to the patients. Applicants have reported by way of Examples in the specification that extracts from *Uncaria tomentosa* are surprisingly effective as amyloid fibril inhibitors, and amyloid fibril inhibition is at least one aspect of treatment of amyloid diseases. This surprising effectiveness of *Uncaria tomentosa* as a therapeutic for amyloid diseases has never been previously suggested; no one else has ever suggested that plant matter from any of the species of *Uncaria* would have any efficacy in the treatment of any amyloid disease. The claims to use of plant matter from *Uncaria* plants for the treatment of Alzheimer's disease and other amyloid diseases are therefore entirely novel, and do not withdraw from the public domain any right to which the public was already, or previously, entitled. The public has never previously had suggested to it that patients with an amyloid disease might benefit from therapeutic quantities of *Uncaria* plant matter, and that suggestion is manifestly not inherent in the Keplinger disclosure.

The Examiner readily acknowledges that Keplinger "does not teach administering the *Uncaria tomentosa* extract for treating amyloid diseases as claimed by applicant". Instead the Examiner asserts that the composition of Keplinger is identical to the claimed composition, and that therefore Keplinger would "inherently have the same effects on the human body as the claimed composition." The Examiner also relies upon two CCPA cases for the propositions that limitations recited in a claim's preamble are allegedly not entitled to patentable weight when they merely recite intended uses of a product fully described in the body of the claim, and that a claim's limitations are allegedly met in the prior art if the prior art structure is capable of performing the intended use.

Applicant asserts that in this case of a pharmaceutical or nutraceutical composition, a novel intended use, regardless of whether the recitation of that use appears in a claim's preamble or not, is a critical limitation of the claim and fully entitled to patentable weight, especially where, as here, the public's pre-existing right is not diminished by the claimed subject matter. The right conferred upon the public (after expiration of Keplinger's patent of course) is the right to administer *Uncaria tomentosa* extracts for immunostimulation as summarized above. Applicant submits that no amount of the immunostimulation use of *Uncaria tomentosa* extracts will infringe

any of the claims here presented, as the claims require explicitly that the *Uncaria* plant matter be expressly selected for its efficacy in treating amyloidoses.

A review of the *Casey* and *Otto* cases cited by the Examiner suggests that these cases are for the most part inapt to the present application. *Casey* dates back to 1967 and addresses a claimed tape dispenser machine that used an identical mechanical structure to that disclosed in a tape perforating machine, and *Otto* addresses a hair curling apparatus the elements of which were presented in various other hair curling devices. Both cases then turned on the propriety of using process- or method-like limitations in an apparatus claim to distinguish over the prior art, a practice then regarded as improper. Significantly, current patent practice does permit such limitations in appropriate circumstances, and it should be regarded to that extent that both *Casey* and *Otto* are thus overruled. In any event, these cases are thus distinguished from the present case and do not suggest or control the outcome of this case.

In addition, the *Casey* and *Otto* cases were addressed strictly to machinery, and Applicant is not aware of any suggestion that composition claims, especially pharmaceutical claims, should be treated as machine-type claims in this regard. Indeed current public policy would weigh against any such similarity of treatment, for the earnest pursuit of cures to some of the worst conditions known to man requires no less than that inventors be encouraged to explore all potential cures, including those involving known compounds suspected of being efficacious in entirely unrelated conditions. And it is only the ultimate grant of patent for such cures that provides such encouragement.

It should be noted that in at least one respect *Casey* actually supports the position of Applicants. In the *Casey* case, upon which the Examiner relies, the court cited and quoted with approval the case of *In re Neugebauer*, 330 F.2d 353, 141 USPQ 205, for the proposition that courts in fact "know no general rule for deciding the weight to be given preambles as positive structural limitations. [emphasis added]" Thus, not only does the *Casey* case not support the Examiner's determination to accord no patentable weight to the express use limitation contained in the preamble to Claim 1, and in the body of Claim 44, *Casey* actually undercuts the Examiner's position. For if there is no general rule as to the force and effect of limitations contained within

claim preambles, then there is no rule that would support ignoring such limitations entirely in determining patentability, as the Examiner has determined to do here.

Indeed, and again in the same *Casey* case relied upon by the Examiner, the *Neugebauer* court is again quoted for saying, "The claims as a whole must be analyzed in light of the disclosure to see if the article defined thereby is distinguishable in fact, *vis-a-vis in verbis*, over the prior art [emphasis added]."

Applicant respectfully submits that this review of the claims "as a whole" "in light of the disclosure" is the correct standard for patentability in cases like this. Applying this correct standard, it is submitted that Claims 1 and 44 and their dependents are fully distinguished over Keplinger because Claims 1 and 44 and their dependents "as a whole", and "in light of the disclosure", define a newly discovered treatment for the dreaded amyloid diseases, including Alzheimer's disease, that was never contemplated or suggested by Keplinger or any other reference of record, and but for the work of the inventors and this patent application disclosure, would perhaps never be disclosed or made available to sufferers of these terrible diseases. Certainly no amount of luck could have contrived to put knowledge of this treatment for Alzheimer's disease into the hands of a reader of Keplinger's patent, and no amount of the administration of Keplinger's immunostimulation compounds could have put knowledge of this treatment for amyloidosis into the hands of any of the patients given his compounds. Claims 1 and 44 and their dependents as a whole define a novel pharmacological agent made from plant material selected for its therapeutic efficacy against the amyloid diseases, whereas Keplinger discusses only immunostimulation compounds that happen to be extracted from the same plant.

The Examiner also makes passing reference to the notion that Keplinger's immunostimulation compounds would "inherently" have the same effect on the human body as the claimed composition. She cites no authority however for the proposition that such inherence somehow defeats or negatives novelty in a claim. Indeed do there appear to be two separate lines of authority with respect to notions of inherence as bars to patentability.

In one line, certain claim elements, not expressly contained in a cited prior art reference are said to be inherently present in the structure disclosed in the reference and that the claim

therefore reads fully upon the reference. This is a line of cases articulating a strong public policy of not depriving or divesting the public of rights arguably already theirs by virtue of a previous public disclosure. For instance in *Atlas Powder v. Ireco*, 190 F.3d 1342; 51 USPQ 2d 1943 (Fed.Cir. 1999), a case involving explosive formulations, certain claimed formula ingredient (aeration) ranges were determined to be inherent in the prior art structures of similar explosives. Implicitly in the *Atlas* case and others like it, the public policy of not depriving the public of rights given in a prior art disclosure is upheld, because it was determined in effect in *Atlas* that every subsequent user or manufacturer of the prior art explosive formulation would necessarily be infringing the new claim if it was allowed over the prior art reference.

But in another line of cases, different from the *Altas* type cases in that no public policy issues are presented, application by the Patent Office of inherence as a ground of rejection is reversed because the mere possibility of inherence is not the same as inherence in fact. For instance in *In re Robertson*, 169 F.3d 743; 49 USPQ 2D 1949 (Fed.Cir. 1999), a case involving diaper fasteners, the court reversed a Board of Patent Appeals affirmation of an inherence rejection of claims, saying, "To establish inherence the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.[emphasis added]" The court also said, "Inherency however may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient. [emphasis added]"

Unlike the facts in *Atlas*, public policy is actually served, not vitiated, by allowing new claims to a cure for Alzheimer's Disease and the like, for the public did not previously have access to such a cure. Thus the *Robertson* case controls here, and Claims 1 and 44 and their relation to the Keplinger reference present a case within the ambit of this *Robertson* type of case. That is, while it might be the case (but which Applicant must here deny, since it is not established and probably can not be established) that a dose of Keplinger's immunostimulation compound could have a therapeutic effect on a patient having an amyloid condition, it is only speculative at best, a mere possibility, and therefore not "necessarily present" in Keplinger's reference. And even if it could be said to be necessarily present, it would certainly not be "so recognized by persons

of ordinary skill". Since "ordinary level of skill" has to be defined prior to the claimed invention, no one skilled in the art as it stood before the present invention would have recognized the anti-amyloid properties of any of Keplinger's immunostimulation compounds. This is just the type of situation contemplated by the *Robertson* court, in that the public is in no danger in this case of losing something they had before; they had *Uncaria* for immunostimulation; now they have *Uncaria* as a treatment for amyloidosis. There is no conflict and no loss of public right, only gain.

Thus under the *Robertson* line of cases, and the correctly understood public policy considerations underlying inherence determinations, "inherence" can not be applied to read into Keplinger's disclosure any efficacy for *Uncaria* extracts as therapeutics for amyloidoses. Since such a surprising efficacy was not necessarily contained in Keplinger's disclosure, and no one skilled in the art would have so recognized any such new efficacy, Claims 1 and 44 and their dependents are therefore distinguished over Keplinger, and this rejection should be reversed.

Indeed in the seminal inherence case of *In re Shetty*, 566 F.2d 81; 195 USPQ 753 (CCPA 1977), a case reversing the Board of Appeals application of the doctrine of inherence as to claims drawn to an appetite suppressant and rejected over an similar compound that functioned as an antiviral agent, the venerable Judge Rich says, "The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown." He also says that inherency "is quite immaterial if ... one of ordinary skill in the art would not appreciate or recognize that inherent result." This view survives to the present and is the same as that expressed in the *Robertson* case discussed above.

Issue 3 The rejection of Claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53 and 54 under 35 USC 102(b) over Stuppner.

Claims 1-6, 9, 10, 12, 13, 44-47, 50, 51, 53 and 54 stand rejected under 35 USC 102b as allegedly anticipated by the Stuppner reference for the same reasons as set forth by the Examiner as to Keplinger above, with the exception that Stuppner discloses only the applicability of his compounds for arthritis, viral diseases and cancer, thus differing from the Keplinger disclosure. Applicants here restate against the Stuppner rejections, as if fully set forth, all of the arguments

made above against the Keplinger rejections, and request that these rejections also be reversed for the same reasons.

Issue 4 The rejection of Claims 1-3, 11, 44-46 and 52 under 35 USC 103(a) over Keplinger and alternatively Stuppner.

Claims 1-3, 11, 44-46 and 52 stand rejected under 35 USC 103 over Keplinger and alternatively Stuppner. The Examiner has argued that either or both of Keplinger and Stuppner references are considered to anticipate all of the claims except dosage claims 11 and 52, but that it is well established that optimizing a dosage of a known composition is obvious. The Examiner further takes the position that a person of ordinary skill in the art would have been motivated to administer a composition containing 70% to 95% of *Uncaria tomentosa* because it well known that varying dosages is a customary practice.

The Examiner acknowledges that neither Keplinger nor Stuppner "teach administering a composition that contains 70 to 95% of *U. tomentosa*" for any purpose whatever, not even for immunostimulation. Instead the Examiner maintains the rejection, asserting that "The amount of an active ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for persons of ordinary skill in the art to employ." Applicant respectfully points out that this kind of "obvious optimalization" rejection has repeatedly been reversed by the reviewing courts. See *In re Yates*, 663 F.2d 1054, 211 USPQ 1149, 1151 (CCPA 1981) ("when the PTO asserts that there is an explicit or implicit teaching or suggestion in the prior art, it must indicate where such a teaching or suggestion appears"); *In re Rijckaert*, 9 F.3d 1531; 28 USPQ 2d 1955 (Fed.Cir. 1993). The Examiner has shown no basis in the art upon which a person of ordinary skill could proceed with such an optimalization, as she is required to do.

In addition, the Examiner's rejection on this ground fails to take into account the fact that all of the base and intervening limitations of Claims 11 and 52 must be read into the respective claims in determining their patentability and, especially in an analysis like this, the accessability, not just of the optimization analysis, but also of <u>all</u> of the claimed limitations must be examined in light of the ordinary level of skill in the art. Thus, while optimization of some known compounds might be sometimes routine, optimization of a limitation in an otherwise novel set of

claim limitations is never routine. *Yates*. Applicant submits that it would certainly not have been obvious in view of either Keplinger or Stuppner to develop a pharmacological agent for treating an amyloid disease in a patient, wherein the agent comprises a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, species *tomentosa*, wherein the plant matter comprises an extract obtained from *Uncaria tomentosa*, the extract being derived from the inner bark or root tissue of *Uncaria tomentosa*, and wherein the weight percentage of plant extract in the agent is in the range of from about 70% to about 95%. Taken as a whole, Claim 11 is not obvious over the cited references, and Applicant requests that these rejections be reversed.

Respectfully submitted,

(206) 343-7074
P07-APP.BRF

PATRICK MICHAEL DWYER
Reg. No. 32,411

ProteoTech, Inc.
1818 Westlake Avenue N, Suite 114
Seattle, WA 98109

APPENDIX TO APPELLANT'S BRIEF (37 CFR 1.192(c)(7))

1. A pharmaceutical agent for treating an amyloid disease in a patient, wherein the pharmacological agent comprises a therapeutically effective amount of plant matter from a plant of the genus Uncaria.

2. The pharmacological agent of claim 1 comprising a therapeutically effective amount of plant matter from a plant of the genus Uncaria, species tomentosa.

3. The pharmacological agent of claim 2 wherein the plant matter comprises an extract obtained from Uncaria tomentosa, the extract being derived from the inner bark or root tissue of Uncaria tomentosa.

4. The pharmacological agent of claim 2 wherein the therapeutically effective amount of Uncaria tomentosa is obtained from a commercially available source.

5. The pharmacological agent of claim 4 wherein commercially available source of Uncaria tomentosa is selected from the group consisting of pills, tablets, caplets, soft and hard gelatin capsules, lozenges, sachets, cachets, vegicaps, liquid drops, elixers, suspensions, emulsions, solutions, syrups, tea bags, aerosols (as a solid or in a liquid medium), suppositories, sterile injectable solutions, sterile packaged powders, bark bundles or bark powder.

6. The pharmacological agent of claim 3 wherein the extract of Uncaria tomentosa comprises an amyloid inhibitory ingredient selected from the group consisting of oxindole alkaloids, quinovic acid glycosides, proanthocyanidins, polyphenols, triterpines, plants sterols, beta-sitosterol, stigmasterol, campesterol, phytosterols, 3-beta, 6beta, 19alpha-trihydroxy-urs-12-en-28-oic-acid, 5alpha-carboxystrictosidine, alloisopteropodine, allopteropodine, angustine, dihydrocorynantheine, dihydrocorynantheine-n-oxide, hirsutine, hirsutine-n-oxide, isomitraphylline, isopteropodine, isorhynchophylline, isorhynchophylline-n-oxide, isorotundifoline, curculogoside, curculigoside B, phenolglucosides, 2-[[2,6-dimethoxybenzoyl)oxy]methyl-4-hydroxyphenyl-beta-D-glucopyranoside, 2-[[2-hydroxy-6-methoxybenzoyl)oxy]methyl-4-hydroxyphenyl-beta-D-glucopyranoside, mitraphylline, oleanolic-acid, pteropodine, quinovic-acid-3beta-o-(Beta-dglucopyranosyl-(1-->3)beta-d-fucopyranosyl-(27-->1)-beta-d-glucopyranosyl-ester, quinovic-acid-3beta-o-beta-d-fucopyranoside,

quinovic-acid-3beta-o-beta-d-fucopyranosyl-(27--> 1)-beta-d-glucopyranosylester, quinovic-acid-3beta-o-beta-d-quinovopyranoside, rhynchophylline, rotundifoline, speciophylline, uncarine, uncarine-f, ursolic acid, cepharanthine (bisbenzylisochinoline alkaloid), berbamine (bisbenzylisochinoline alkaloid), matrine (lupine alkaloid), pilocarpine (imidazole alkaloid), 2,3-Dihydroxybenzoic acid, ferulic acid, anethole, cleistanthine (lignane), phenolglucosides, urunshiole, alpha-tocopherole (vitamin E), ubichone, maesanine, zexbrevine A/B, 12-O-tetradeoanoyl-phorbol-13-acetate, TPA (tetracyclic diterpene), saponine with aglycone oleonic acid (pentacyclic triterpene), and cynonchoside.

7. The pharmacological agent of claim 2 wherein the therapeutically effective amount of Uncaria tomentosa comprises a dosage in the range of from about 10 to 1,000 mg/kg of body weight of the patient.

8. The pharmacological agent of claim 7 wherein the therapeutically effective amount of Uncaria tomentosa comprises a dosage in the range of from about 10 to 100 mg/kg of body weight of the patient.

9. The pharmacological agent of claim 1 wherein said amyloid disease for treatment is selected from the group consisting of the amyloid associated with Alzheimer's disease, Down's syndrome and hereditary cerebral hemorrhage with amyloidosis of the Dutch type (wherein the specific amyloid is referred to as beta-amyloid protein or Aß), the amyloid associated with chronic inflammation, malignancy and Familial Mediterranean Fever (wherein the specific amyloid is referred to as AA amyloid or inflammation-associated amyloidosis), the amyloid associated with multiple myeloma and other B-cell dyscrasias (wherein the specific amyloid is referred to as AL amyloid), the amyloid associated with type II diabetes (wherein the specific amyloid is referred to as amylin or islet amyloid), the amyloid associated with the prion diseases including Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, kuru and animal scrapie (wherein the specific amyloid is referred to as PrP amyloid), the amyloid associated with long-term hemodialysis and carpal tunnel syndrome (wherein the specific amyloid is referred to as $beta_2$-microglobulin amyloid), the amyloid associated with senile cardiac amyloid and Familial Amyloidotic Polyneuropathy (wherein the specific amyloid is referred to as transthyretin or

prealbumin), and the amyloid associated with endocrine tumors such as medullary carcinoma of the thyroid (wherein the specific amyloid is referred to as variants of procalcitonin).

10. The pharmacological agent of claim 9 wherein said amyloid disease for treatment is Alzheimer's Disease.

11. The pharmaceutical agent of claim 3 wherein the weight percentage of plant extract in the agent is in the range of from about 70% to about 95%.

12. The pharmaceutical agent of claim 1 further comprising a pharmaceutically acceptable carrier, diluent or excipient.

13. The pharmaceutical agent of claim 2 wherein the therapeutically effective amount of plant matter has an amyloid inhibitory activity or efficacy greater than 50%.

44. A pharmacological agent comprising a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*, the plant matter and the therapeutic amount of the plant matter selected for efficacy in treating an amyloid disease in a patient.

45. The pharmacological agent of claim 44 wherein the plant of the genus *Uncaria* is a plant of the genus *Uncaria*, species *tomentosa*.

46. The pharmacological agent of claim 45 wherein the plant matter comprises an extract obtained from *Uncaria tomentosa*, the extract being derived from the inner bark or root tissue of *Uncaria tomentosa*.

47. The pharmacological agent of claim 46 wherein the extract of *Uncaria tomentosa* comprises an amyloid inhibitory ingredient selected from the group consisting of oxindole alkaloids, quinovic acid glycosides, proanthocyanidins, polyphenols, triterpines, plants sterols, beta-sitosterol, stigmasterol, campesterol, phytosterols, 3-beta, 6beta, 19alpha-trihydroxy-urs-12-en-28-oic-acid, 5alpha-carboxystrictosidine, alloisopteropodine, allopteropodine, angustine, dihydrocorynantheine, dihydrocorynantheine-n-oxide, hirsutine, hirsutine-n-oxide, isomitraphylline, isopteropodine, isorhynchophylline, isorhynchophylline-n-oxide, isorotundifoline, curculogoside, curculigoside B, phenolglucosides, 2-[[2,6-dimethoxybenzoyl)oxy]methyl-4-hydroxyphenyl-beta-D-glucopyranoside, 2-[[2-hydroxy-6-methoxybenzoyl)oxy]methyl-4-hydroxyphenyl-beta-D-glucopyranoside,

mitraphylline, oleanolic-acid, pteropodine, quinovic-acid-3beta-o-(Beta-dglucopyranosyl-(1--> 3)beta-d- fucopyranosyl-(27--> 1)-beta-d-glucopyranosyl-ester, quinovic-acid-3beta-o-beta-d-fucopyranoside, quinovic-acid-3beta-o-beta-d-fucopyranosyl-(27--> 1)-beta-d-glucopyranosylester, quinovic-acid-3beta-o-beta-d-quinovopyranoside, rhynchophylline, rotundifoline, speciophylline, uncarine, uncarine-f, ursolic acid, cepharanthine (bisbenzylisochinoline alkaloid), berbamine (bisbenzylisochinoline alkaloid), matrine (lupine alkaloid), pilocarpine (imidazole alkaloid), 2,3-Dihydroxybenzoic acid, ferulic acid, anethole, cleistanthine (lignane), phenolglucosides, urunshiole, alpha-tocopherole (vitamin E), ubichone, maesanine, zexbrevine A/B, 12-O-tetradeoanoyl-phorbol-13-acetate, TPA (tetracyclic diterpene), saponine with aglycone oleonic acid (pentacyclic triterpene), and cynonchoside.

48. The pharmacological agent of claim 46 wherein the therapeutically effective amount of *Uncaria tomentosa* comprises a dosage in the range of from about 10 to 1,000 mg/kg of body weight of the patient.

49. The pharmacological agent of claim 48 wherein the therapeutically effective amount of *Uncaria tomentosa* comprises a dosage in the range of from about 10 to 100 mg/kg of body weight of the patient.

50. The pharmacological agent of claim 44 wherein said amyloid disease for treatment is selected from the group consisting of the amyloid associated with Alzheimer's disease, Down's syndrome and hereditary cerebral hemorrhage with amyloidosis of the Dutch type (wherein the specific amyloid is referred to as beta-amyloid protein or Aß), the amyloid associated with chronic inflammation, various forms of malignancy and Familial Mediterranean Fever (wherein the specific amyloid is referred to as AA amyloid or inflammation-associated amyloidosis), the amyloid associated with multiple myeloma and other B-cell dyscrasias (wherein the specific amyloid is referred to as AL amyloid), the amyloid associated with type II diabetes (wherein the specific amyloid is referred to as amylin or islet amyloid), the amyloid associated with the prion diseases including Creutzfeldt-Jakob disease, Gerstmann-Straussler syndrome, kuru and animal scrapie (wherein the specific amyloid is referred to as PrP amyloid), the amyloid associated with long-term hemodialysis and carpal tunnel syndrome (wherein the specific amyloid is referred to

as $beta_2$-microglobulin amyloid), the amyloid associated with senile cardiac amyloid and Familial Amyloidotic Polyneuropathy (wherein the specific amyloid is referred to as transthyretin or prealbumin), and the amyloid associated with endocrine tumors such as medullary carcinoma of the thyroid (wherein the specific amyloid is referred to as variants of procalcitonin).

51. The pharmacological agent of claim 50 wherein said amyloid disease for treatment is Alzheimer's Disease.

52. The pharmaceutical agent of claim 46 wherein the weight percentage of plant extract in the agent is in the range of from about 70% to about 95%.

53. The pharmaceutical agent of claim 46 further comprising a pharmaceutically acceptable carrier, diluent or excipient.

54. The pharmaceutical agent of claim 46 wherein the therapeutically effective amount of plant matter has an amyloid inhibitory activity or efficacy greater than 50%.